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(54) Title: PREVENTION/RETARDATION OF HAIR GROWTH

(57) Abstract

A composition and method for retarding or preventing hair growth, wherein the composition includes a) citric acid, b) an electrolyte, and c) a cosmetically acceptable aqueous vehicle which includes a film forming agent.

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Prevention/Retardation Of Hair Growth

Technical Field

The present invention relates to a composition and method for the retardation or prevention of hair growth.

Background Art

In the past, there has been great emphasis on methods and compositions relating to the inhibition of unwanted hair growth in humans. In particular, for cosmetic reasons it is desirable to remove unwanted hair from parts of the body such as the legs, armpits and face without recourse to shaving.

The products that are currently available for topical use in the removal of unwanted hair are mostly based on thioglycollates as the active ingredient. Examples of products containing thioglycollates are available under the trade names "VEET" and "NAIR". Thioglycollates function as reducing agents at high pH by reducing disulfide bonds in hair. Following penetration into the follicular canal, the hair is weakened in the region above the keratinizing zone. The hair shaft may then be broken off just below the skin surface leaving a soft, smooth skin surface.

Hair growth does not however cease and, since the hair is broken near the surface, regrowth occurs within a relatively short time and the cosmetic advantage is thus rapidly lost. Retreatment with the thioglycollate product is necessary if the treated skin is to be maintained in a hairless condition. There is consumer resistance to the continual use of thioglycollate hair removal product as skin irritation is sometimes encountered. However, as no alternative methods of hair removal exist apart from shaving and plucking (including the use of tweezers, forceps and waxing) of individual hairs, in the past thioglycollate-containing products have offered the most effective method, particularly for women, for the removal of unwanted hair from the body surface.

The present inventors have surprisingly found a method and a composition which when applied topically to the skin retards or prevents hair growth. The inventors have found that the method and composition cause the hair growth to be finer, thinner, shorter and much less visible. Typically, coarse hair is replaced by vellus hair. With repeated application the inventors of the present invention have found that hair growth may be prevented entirely.

Disclosure of Invention

In a first aspect, the present invention consists in a composition for retarding or preventing hair growth including:

(a) citric acid;

(b) an electrolyte; and

(c) a cosmetically acceptable aqueous vehicle which includes a film forming agent.

In a second aspect, the present invention consists in a method for retarding and/or preventing hair growth comprising applying a composition which includes:

(a) citric acid;

(b) an electrolyte; and

(c) a cosmetically acceptable aqueous vehicle which includes a film forming agent;

to an area of skin in which hair growth occurs and allowing the composition to contact the skin for a time sufficient so as to effectively prevent or retard hair growth.

In a third aspect, the present invention is directed to the use of a composition as defined in the first aspect of the invention for preventing or retarding hair growth.

The concentration of citric acid may be greater than 30% w/w. Preferably, the concentration of citric acid will be in the range of 1 to 30% w/w and more preferably 5 to 20% w/w.

The electrolyte may be selected from a variety of compounds including alkali metal and alkali earth metal salts that are water soluble. Preferably the electrolyte is sodium chloride and more preferably Dead Sea Salt. The electrolyte may be present in a concentration of greater than 20% w/w. Preferred concentrations of electrolyte are in the range of 1 to 20% w/w and more preferably 5 to 10% w/w.

The cosmetically acceptable aqueous vehicle acts as a diluent, dispersant or carrier for other materials present in the composition, so as to facilitate the distribution of the composition when applied to the relevant area of skin. Suitable vehicles include emulsions, microemulsions or an aqueous solution or dispersion of a film forming agent.

The film forming agent may be selected from a variety of ingredients including liquid or solid emollients, emulsifiers, surface active agents, gums,

humectants, thickeners, powders and protein solutions. These agents can be used singly or as mixtures of one or more agents. Preferably the film forming agent is present in a concentration in the range of 0.05 to 40% w/w.

Emollients, such as mineral oil, fatty alcohols, alkyl esters, silicones and silicone derivatives may be employed in the present invention. Fatty alcohols may be selected from stearyl alcohol and cetyl alcohol. Alkyl esters may be selected from octyl palmitate, decyl oleate and isopropyl myristate. Silicones and silicone derivatives may be selected from phenyl dimethicone, dimethicone and simethicone. It will be appreciated, however, that the present invention is not limited to the aforementioned emollients.

The composition of the present invention may optionally comprise one or more emulsifiers/surface active agents, the choice of which will normally determine whether a water-in-oil emulsion or an oil-in-water emulsion is formed. Emulsions preferably contain 3.0 to 10% w/w of emulsifiers and more preferably 0.5 to 15% w/w. Microemulsions preferably contain 0.5 to 35% w/w of surface active agents and more preferably 15 to 28% w/w.

Emulsifiers, such as mixtures of glyceryl stearate and PEG-100 stearate (Lipomulse 165 and Arlacel 165), Tegocare PS (methyl glucose sesquistearate), PEG7 hydrogenated castor oil (Arlacel 989) and glyceryl sorbitan oleostearate (Arlacel 481) can be employed in the present invention. It will be appreciated, however, that the present invention is not limited to the aforementioned emulsifiers.

Surface active agents for microemulsions may be selected from Lipocol SC20 (Ceteareth-20), Ameroxol OE20 (Oleth-20), Lipocol L4 (Laureth-4), Amerchol L101 (Lanolin alcohol and mineral oil), Cetiol HE (PEG 7 glyceryl cocoate) and Liponic EG1 (Glycereth-20). It will be appreciated, however, that the present invention is not limited to the aforementioned surface active agents.

The composition of the present invention may be preserved by humectants which act as water activity depressants. Humectants such as glycerol and polylethylene glycols may be employed in the present invention. Preferably, the humectant is present in a concentration of between 1 to 5% w/w. It will be appreciated, however, that the present invention is not limited to the aforementioned humectants.

A variety of gums including Sclerotium gum (Amigel) may be used in the present invention. Amigel is an effective polymer film forming agent and is preferably present in a concentration of 0.1 to 2% w/w.

Powders such as clays, silicas, talc and starch may be employed in the present invention. A variety of clays may be used including bentone. Silicas are preferably fumed silicas.

A variety of protein solutions may be used including beer.

It will be appreciated, however, that the present invention is not limited to the aforementioned electrolytes and film forming agents.

The composition according to the present invention may optionally comprise one or more conventional antiperspirant or deodorant active substances. Compositions according to the present invention can thus be used regularly on the underarm not only to prevent unwanted hair growth but also to reduce or eliminate perspiration and/or to reduce or eliminate malodour. Examples of conventional antiperspirant actives include astringent metallic salts such as aluminium chloride, aluminium chlorohydrate and zirconium chlorohydrate. A suitable deodorant is triclosan (Irgasan DP 300).

The pH of the composition of the present invention is preferably below 4.

The composition of the present invention may take the form of a cream, lotion, gel or spray.

The composition of the present invention may be topically applied to a selected area of the body in which it is desired to inhibit hair growth. For example, the composition can be applied to the face, neck, upper lip, chin, legs, arms, torso and armpits.

According to the method of the present invention, the time sufficient to effectively prevent or retard hair growth is at least 30 minutes per application. Preferably, the time sufficient to effectively prevent or retard hair growth is 4h to 12h per application.

Preferably, the composition is applied to an area of skin which has previously been subjected to mechanical depilation such as waxing or shaving or chemical depilation. In that case, the time sufficient to effectively prevent or retard hair growth is at least 5 minutes per application. Preferably, the time sufficient to effectively prevent of retard hair growth is 4h to 12h per application.

The composition is preferably applied to and left on an area of skin three times a week, preferably daily and even more preferably twice daily. Preferably, the composition once applied to the skin is not specifically removed but may be removed during daily washing rituals. Reduction of hair growth is demonstrated when the frequency or hair removal is reduced or the subject perceives less hair on the treated site or quantitatively, when the weight of hair removed by shaving (that is hair mass) is reduced.

It will be appreciated, however, that the time sufficient to prevent or retard hair growth may vary outside the preferred times depending on factors such as, the individuals volume of hair, genetic make up, frequency of washing etc.

Modes for Carrying Out the Invention

The following examples illustrate compositions in accordance with the first aspect of the invention, which are suitable for topical application to an area of skin for retardation/prevention of hair growth in accordance with the second aspect of the present invention.

Example 1

Ingredients	% w/w
Sodium chloride	3.0
Citric acid	10.0
Lipomulse 165	0.5
Amigel	0.6
Propylene glycol	3.0
Water	to 100

The citric acid and sodium chloride were dissolved in water with heating and stirring. Lipomulse 165 was added and the solution heated to 50°C and stirred to disperse the Lipomulse 165. A paste of Amigel and propylene glycol was slowly added to the water solution with stirring. Care was taken not to create a turbulence during mixing so as to avoid aeration. The resulting solution was cooled to room temperature and the composition was obtained as a translucent lotion.

Examples 2, 3, 4

Ingredients	Example 2 %w/w	Example 3 %w/w	Example 4 %w/w
Citric acid	22.0	22.0	22.0
Dead sea salt	6.2	6.2	6.2
Lipomulse 165	0.5	0.5	0.5
Amigel	0.6	1.2	2.4
Propylene glycol	3.0	3.0	3.0
Water	to 100	to 100	to 100

The procedure outlined for Example 1 was employed to make the compositions according to Examples 2, 3 and 4. Example 2 was obtained as a lotion, Example 3 as a soft gel and Example 4 as a firm gel. Example 2 retained its viscosity and emulsion stability for at least 2 months at 45°C.

Example 5

Ingredients	% ww
Tegocare PS	4.0
Octyl Palmitate	8.5
Decyl Oleate	8.5
Arlacel 165	2.0
Stearyl Alcohol	2.0
Glycerol	2.0
Water	54.4
Citric Acid	10.0
NaCl or Dead Sea Salt	5
Sodium Hydroxide to pH 3.5	to 100

Tegocare PS, octyl palmitate, decyl oleate, Arlacel 165 and stearyl alcohol were combined and heated to 80°C. This solution was added to a mixture of glycerol and water at a temperature of 80°. The combined solution were mixed at a low speed with a mechanical stirrer. The resulting

solution was cooled to 35 to 40° and a mixture of water, citric acid and sodium hydroxide added. The solution was cooled to room temperature and the composition according to Example 5 was obtained as an opaque oil in a water emulsion. The final product was obtained as a white lotion.

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Ingredient Availability

Ingredients	Chemical Name	Available from:
Citric Acid	-	Ajax Chemicals
Sodium chloride	-	Ajax Chemicals
Dead sea salt	-	Alban Huller Int
Sodium Hydroxide	-	ICI Australia
Mineral oil		Exxon
Cetyl alcohol	-	Lipo-Australian agents Bronson and Jacobs P/L
Stearyl alcohol	-	Lipo-Australian agents Bronson and Jacobs P/L
Octyl palmitate		Stepan
Decyl oleate	-	Goldschmidt
Phenyl dimethicone	-	Dow Corning
Dimethicone	-	Dow Corning
Simethicone	-	Dow Corning
Arlacel 165	mixture of glyceryl stearate and PEG-100 stearate	Lipo-Australian agents Bronson and Jacobs P/L
Lipomulse 165	mixture of glyceryl stearate and PEG-100 stearate	Lipo-Australian agents Bronson and Jacobs P/L
Arlacel 989	PEG-7 hydrogenated castor oil	ICI Australia
Arlacel 481	glyceryl sorbitan oleostearate	ICI Australia
Tegocare PS	Methyl Glucose sesquistearate	Goldschmidt

Ingredients	Chemical Name	Available from:
Lipocol SC20	Ceteareth-20	Lipo-Australian agents Bronson and Jacobs P/L
Ameroxol OE20	Oleth-20	Amerchol-Australian agents Bronson and
Lipocol L4	Laureth-4	Lipo-Australian agents Bronson and Jacobs P/L
Amerchol L101	Lanolin alcohol and mineral oil	Amerchol-Australian agents Bronson and
Cetiol HE	PEG-7 glyceryl cocoate	Henkel Australia
Liponic EG1	Glycereth-20	Lipo-Australian agents Bronson and Jacobs P/L
Glycerol	-	Unichema
Polyethylene glycol	-	Stepan
Amigel	Sclerotium gum	Alban Muller Int.
Aluminium chloride	-	Bronson and Jacobs P/L
Aluminium chlorohydrate	-	Bronson and Jacobs P/L
Zirconium chlorohydrate	-	Bronson and Jacobs P/L
Irgasan DP 300	Triclosan	Ciba-Geigy Australia Ltd

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

CLAIMS

1. A composition for retarding or preventing hair growth including:

(a) citric acid,

(b) an electrolyte, and

(c) a cosmetically acceptable aqueous vehicle which includes a film forming agent.

2. The composition according to claim 1 wherein the citric acid is in a concentration of 1 to 30% w/w.

3. The composition according to claim 1 or 2 wherein the citric acid is in a concentration of 5 to 20% w/w.

4. The composition according to any one of claims 1 to 3 wherein the electrolyte is selected from the group consisting of alkali metal and alkali earth metal salts that are water soluble.

5. The composition according to any one of claims 1 to 4 wherein the electrolyte is sodium chloride.

6. The composition according to any one of claims 1 to 4 wherein the electrolyte is Dead Sea Salt.

7. The composition according to any one of claims 1 to 6 wherein the electrolyte is present in a concentration of 1 to 20% w/w.

8. The composition according to any one of claims 1 to 7 wherein the electrolyte is present in a concentration of 5 to 10% w/w.

9. The composition according to any one of claims 1 to 8 wherein the cosmetically acceptable aqueous vehicle is selected from the group consisting of emulsions, microemulsions or an aqueous solution or dispersion of a film forming agent.

10. The composition according to any one of claims 1 to 9 wherein the film forming agent is present in a concentration of 0.05 to 40% w/w.

11. The composition according to any one of claims 1 to 10 wherein the film forming agent is selected from one or more of the group consisting of emollients, emulsifiers, surface active agents, gums, humectants, thickeners, powders and protein solutions.

12. The composition according to claim 11 wherein the emollient is selected from the group consisting of mineral oil, fatty alcohols, alkyl esters, silicones and silicone derivatives.

13. The composition according to claim 12 wherein the fatty alcohol is selected from the group consisting of stearyl alcohol and cetyl alcohol.

14. The composition according to claim 12 wherein the alkyl ester is selected from the group consisting of octyl palmitate, decyl oleate and isopropyl myristate.

15. The composition according to claim 12 wherein the silicones and silicone derivatives are selected from the group consisting of phenyl dimethicone, dimethicone and simethicone.

16. The composition according to any one of claims 11 to 15 wherein the emulsifiers are in a concentration of 3.0 to 10% w/w.

17. The composition according to any one of claims 11 to 16 wherein the emulsifiers are in a concentration of 0.5 to 15% w/w.

18. The composition according to any one of claims 11 to 17 wherein the surface active agents is in a concentration of 0.5 to 35% w/w.

19. The composition according to any one of claims 11 to 18 wherein the surface active agents is in a concentration of 15 to 28% w/w.

20. The composition according to any one of claims 11 to 19 wherein one or more emulsifiers is selected from the group consisting of glyceryl stearate and PEG-100 stearate and mixtures thereof, methyl glucose sesquistearate, PEG-7 hydrogenated castor oil and glyceryl sorbitan oleostearate.

21. The composition according to any one of claims 11 to 20 wherein the surface active agent is selected from the group consisting of Ceteareth-20, Oleth-20, Laureth-4, mixtures of lanolin alcohol and mineral oil, PEG-7 glyceryl cocoate and Glycereth-20.

22. The composition according to any one of claims 11 to 21 wherein the humectant is selected from the group consisting of glycerol and polylethylene glycols.

23. The composition according to any one of claims 11 to 22 wherein the humectant is present in a concentration of 1 to 5% w/w.

24. The composition according to any one of claims 11 to 23 wherein the gum is Sclerotium gum.

25. The composition according to any one of claims 11 to 24 wherein the gum is in a concentration of 0.1 to 2% w/w.

26. The composition according to any one of claims 11 to 25 wherein the powder is selected from the group consisting of clays, silicas, talc and starch.

27. The composition according to any one of claims 1 to 26 which further includes one or more antiperspirant or deodorant active substances.

28. The composition according to claim 27 wherein the antiperspirant actives are astringent metallic salts.

29. The composition according to claim 28 wherein the astringent metallic salts are selected from the group consisting of aluminium chloride, aluminium chlorohydrate and zirconium chlorohydrate.

30. The composition according to any one of claims 1 to 29 wherein the pH of the composition is below 4.

31. The composition according to any one of claims 1 to 30 wherein the composition is in the form of a cream, lotion, gel or spray.

32. A method for retarding and/or preventing hair growth comprising applying a composition according to any one of claims 1 to 31 to an area of skin in which hair growth occurs and allowing the composition to contact the skin for a time sufficient so as to effectively prevent or retard hair growth.

33. The method according to claim 32 wherein the time sufficient to effectively prevent or retard hair growth is at least 30 minutes per application.

34. The method according to claim 33 wherein the time sufficient to effectively prevent or retard hair growth is 4h to 12h per application.

35. The method according to claim 32 wherein the area of skin has previously been subjected to depilation.

36. The method according to claim 35 wherein the area of skin has been subjected to chemical depilation.

37. The method according to claim 35 wherein the area of skin has been subjected to mechanical depilation.

38. The method according to any one of clams 35 to 37 wherein the time sufficient to effectively prevent or retard hair growth is at least 5 minutes per application.

39. The method according to clam 38 wherein the time sufficient to effectively prevent or retard hair growth is 4h to 12h per application.

40. Use of a composition as defined in any one of claims 1 to 31 for preventing or retarding hair growth.

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 98/00374

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl[6]: A61K 7/06, 7/155

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC: A61K 7/06, 7/155

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AU: IPC as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPAT : SALT, NACL, SODIUM CHLORIDE, CITRIC ACID
CAPLUS :

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5100656 A (LANG et al) 31 March 1992 column 5, example 3	1-31
X	US 4321156 A (BUSHMAN) 23 March 1982 columns 3-4	1-31
X	US 4253993 (RAMSEY, III et al) 3 March 1981 column 4	1-31

☒ Further documents are listed in the continuation of Box C

☐ See patent family annex

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Date of the actual completion of the international search
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INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 98/00374

C (Continuation) **DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 739621 A (KAO CORPORATION) 30 October 1996 page 3	1-31
X	EP 182369 A (S C JOHNSON & SON INC) 28 May 1986 pages 11-13	1-31
X	Derwent abstract Accession No: 90-296104/39, Class D21, SU 1528-494-A (CHEM IND RES DES) 15 December 1989	1-31
X	Gamez-Garcia M, Journal of the Society of Cosmetic Chemists., Vol 44 (2) 1993 pages 69-87. "Effects of some oils,emulsions, and other aqueous systems on the mechanical properties of hair at small deformations." Whole document.	1-31

INTERNATIONAL SEARCH REPORT
Information on patent family members

International Application No.
PCT/AU 98/00374

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	5100656	CA	2001271	DK	1527/90	EP	365825
		FI	902826	NO	902803	WO	90/04382
US	4321156	AR	217839	AU	34563/78	CA	1100044
		FR	2385793	GB	1567742	IT	1156180
US	4253993	CA	1116524	GR	66436	JP	55023176
EP	739621	JP	8310919	US	5716605		
EP	182369	AU	50060/85	BR	8503774	JP	61159500
		US	4603005				

END OF ANNEX